

REMARKS

I. Interview with the Examiner

Applicants thank the Examiner for the telephone interview conducted with the Examiner on September, 12, 2008. The topic of the interview focused on the 35 U.S.C. §102(e) rejections concerning the “integrated electronic instrumentation” as presently recited in claims 1-32, 33-51 and 54. The Examiner suggested various helpful amendments to the method claims, which have been made to the pending claims.

SUMMARY OF CLAIMS

Claims 33-51 and 54 are currently pending. Claims 1-32, 52 and 53 are cancelled. Claims 33, 42, 43, 47, and 51 are currently amended. No new matter has been added. Reconsideration is respectfully requested in light of the following.

The amendments to claims 33, 42, 43, 47, and 51 are supported throughout the specification, but specifically by:

Figures 1, 7 and 8, original claim 3; paragraphs 0009, 0031, and 0034.

I. Claim rejections under 35 U.S.C. 102(e)

The Examiner rejected pending claims 33-41 and 51-54 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,682,440; Karidis et al. Applicants respectfully traverse the rejection for the reasons set forth below.

The prior pending claims are not anticipated by Karidis et al. However in order to advance prosecution claims 33 and 51 have been amended to describe the claimed invention in greater clarity. The new or amended claims are directed to methods of using a paper diary: *wherein said paper diary is a binder; wherein said electronic instrumentation is incorporated into an outer casing of the paper diary and is hidden from a subject's view; wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary.*

Karidis et al. is directed towards a laptop device which comprises a keyboard and a graphical display and/or a separate tablet entry system (See Figures 1—40). In contrast, the pending claims are directed to methods of monitoring a clinical trial, using a paper diary that is a binder comprising a hidden electronic instrumentation that is not apparent to a user, wherein the paper diary further comprises a sensor that detects when the user uses the diary. Karidis et al. does not disclose a method of using a paper diary as presently claimed.

Applicants respectfully request that in view of the amended claims the rejection under 35 U.S.C. 102(e) be withdrawn.

II. Claim rejections under 35 U.S.C. 103(a)

The Examiner has rejected pending claims 47-48 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,362,440, Karidis et al. Further, the Examiner has rejected claims 42-46 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,362,440, Karidis et al., as applied to claims 47-48 above, and further in view of non-patent literature article “Diary keeping in asthma: comparison of written and electronic methods” Hyland, et al., which is hereinafter referred to as Hyland et al.

The prior pending claims are not rendered unpatentable by Karidis et al., alone or in view of Hyland, et al. However, in order to advance prosecution claims 42, 43, and 47 have been amended to describe the claimed invention with greater clarity.

Karidis et al. has been summarized above. The teachings of Hyland, et al., do not supplement Karidis et al. in such a way as to cure the failure to teach a method of using a paper diary that is a binder comprising a hidden electronic instrumentation that is not apparent to a user, wherein the paper diary comprises a sensor that detects when the user uses the diary.

The examiner has noted that Karidis et al. fails to teach the recordation of clinical trial data (OA 6/16/08; pg. 6). Hyland et al., is directed to records kept by Asthma patients and does not disclose a method of clinical trial monitoring as presently claimed in independent claims 33, 42, 47, and 51. Therefore, Hyland et al. fails to compensate for the deficiencies of Karidis et al.

Applicants respectfully request that in view of the amended claims the rejection under 35 U.S.C. 103(a) be withdrawn.

CONCLUSION

Applicants respectfully request reconsideration and allowance of claims 33-51 and 54. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned agent at (202) 973-8870. The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 31886.706.201).

Respectfully submitted,

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By:



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